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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,975	09/15/2003	Mitchell P. Fink	3403.1001-007	2253
21005	7590	07/01/2004	EXAMINER	
HAMILTON, BROOK, SMITH & REYNOLDS, P.C. 530 VIRGINIA ROAD P.O. BOX 9133 CONCORD, MA 01742-9133			HENLEY III, RAYMOND J	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 07/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/662,975	Applicant(s) FINK ET AL.	
	Examiner Raymond J Henley III	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-31 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 15 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/11/2004</u> . | 6) <input type="checkbox"/> Other: ____. |

CLAIMS 1-31 ARE PRESENTED FOR EXAMINATION

Applicants' Preliminary Amendment and Information Disclosure Statement filed February 11, 2004 have been received and entered into the application. Accordingly, the specification at page 14, line 23 through page 15, line 10 has been amended. Also, as reflected by the attached, completed copy of form PTO-1449 (1 page), the cited references have been considered.

Claim Objection

Claims 12 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claim 1 fails to provide antecedent basis for the requirement of claim 12 for "said divalent cation...".

Applicant is required to either cancel the claim, amend the claim to place it in proper dependent form, or rewrite the claim in independent form..

Claim Rejection - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating a cytokine-mediated inflammatory condition in a patient suffering therefrom, does not reasonably provide enablement for the general treatment of a patient who is suffering from a cytokine-mediated inflammatory condition. The specification

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does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The therapeutic objective that is set forth in claims 1 and 16 modifies the intended host rather than the therapeutic objective of "treating". Such reads on a panacea, i.e., treating the patient for any and all purposes, and the art currently is unaware of any single agent, or combination of agents that could be used for the treatment of any and all disease states which is encompassed by the present claims.

In order to overcome this rejection, applicant may wish to consider amending claims 1 and 16 to read, in part, ---A method for treating a cytokine-mediated inflammatory condition in a patient suffering therefrom, said method comprising the steps of...---

Claim Rejection - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4 and 5 rejected under 35 U.S.C. 102(e) as being anticipated by Greenway et al. (U.S. Patent No. 6,417,231, cited by the Examiner) who teach glyceryl esters of pyruvic acid for the treatment of asthma (see the abstract and col. 5, lines 33-42).

Claim Rejection - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 4-13, 15-17, 19-31 are rejected under 35 U.S.C. 103(a) as being obvious over Katz (U.S. Patent No. 5,798,388, cited by Applicants) in view of Ajami et al. (U.S. Patent Application Publication No. 2003/0073743, cited by the Examiner).

The applied reference, i.e., Ajami et al., has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This reference may be removed as applicable prior art by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a

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terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

Katz teaches a method for treating a disease state in mammals caused by mammalian cells involved in the inflammatory response that comprises the administration of an inflammatory mediator which may be a pyruvate precursor and a carrier which may be an isotonic liquid or in the form of tablets, capsules, liquids, enteric tablets and capsules, parenterals, topicals, creams, gels, ointments, chewing gums, confections and the like (see the abstract and col. 7, lines 20-56). The inflammatory response referred to by Katz may be due to cytokine production (col. 7, line 17), asthma is shown as an inflammatory disease (col. 7, line 66-67) and Katz exemplifies pyruvate esters as pyruvate precursors (col. 7, lines 31-35).

The differences between the above and the claimed subject matter lies in that Katz fails to teach:

(1) the presently claimed pyruvate esters, the carrier being Ringer's solution of saline supplemented with potassium ion having a pH ranges of 7-8 or the additional presence of a divalent cation such as calcium or magnesium; and

(2) each of the inflammatory diseases claimed and the administration of the active agent 24 hours after the onset of the inflammatory disease.

However, to the skilled artisan, the claimed subject matter would have been obvious because:

(1) Katz teaches that esters of pyruvic acid may be utilized and simple, alkyl esters of pyruvic acid would have been immediately appreciated by the skilled artisan as being useful therefor given the elementary nature of alkyl esters of carboxylic acids. Moreover, Ajami et al. teach the presently claimed pyruvic acid esters as being known (abstract, Figure 2 and page 2, lines 1-3 of section [0019] and section [0020]) and a carrier therefor which is any carrier generally recognized as being safe for administering a therapeutic agent to a mammal (page 2, section [0018]-[0019]. The skilled artisan would have been motivated to employ these pyruvic acid esters because Katz teaches that pyruvic acid esters would be useful as pyruvic acid precursors and Ajami et al. teach that the esters are biologically safe and readily hydrolysable (page 3, section [0022]). Additionally, the skilled artisan would have been motivated to employ as the carrier Ringer's solution of saline supplemented with potassium ion having a pH range of 7-8 or the additional presence of a divalent cation such as calcium or magnesium because Ajami et al teach these very features as being apart of the carrier which is taught to be safe for administering a therapeutic agent to a mammal (page 2, section [0019]).

(2) Katz teaches cytokine related inflammatory diseases in general and the identification and subsequent treatment of any such disease from those known to the skilled artisan would have been a matter well within the purview of the skilled artisan and the artisan would have been motivated to do so because Katz indicates that the pyruvate esters are useful for cytokine related inflammatory diseases in general. Also, the determination to administer the pyruvate esters at 24 hours after the onset of the inflammatory disease would have been well within the purview of the skilled artisan, especially in cases where the patient suffering from such a disease did not present to the practitioner until 24 hours after the onset of the disease.


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Accordingly, for the above reasons, the claims are deemed properly rejected and none are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Raymond J Henley III
Primary Examiner
Art Unit 1614

June 25, 2004